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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/165,522	10/02/98	DAVIS R	10363/005001

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EXAMINER	
RAO, M	
ART UNIT	PAPER NUMBER
1652	13

DATE MAILED: 09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/165,522	Davis et al.
Examiner	**Group Art Unit**
Manjunath N. Rao	1652

☒ Responsive to communication(s) filed on *Jun 7, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-17* is/are pending in the applicat

Of the above, claim(s) *7-17* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 ✓

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4* ✓

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-6 in Paper No. 8, dated 4-17-2000 is acknowledged. Accordingly, claims 1-6 are now at issue and are present for examination.

2. Claims 7-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by McKay et al. (US 5,877,309 dated 3-2-1999, filed on 8-13-1997). This rejection is based upon the public availability of a patent. Claims 1-2 of the instant application are drawn to a method of identifying a compound that modulates JNK3 expression. McKay et al. disclose a method for assaying modulation of expression of a gene encoding a JNK protein including JNK1, JNK2 and JNK3 (see particularly, examples 2-5). McKay et al. disclose oligonucleotides capable of hybridizing to nucleic acids encoding JNK1-3 and modulating the expression of JNK proteins. (See abstract and the entire document). Thus McKay et al. anticipate claims 1-2 of this application as written.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay et al. in view of Chauhan et al. (Blood, Jan 1, 1997, Vol. 89:227-234). Claims 3-4 are drawn to a method of identifying a compound that modulates JNK3 activity in a cell. McKay et al. teach JNK3 and method of modulation of its expression in a cell line. However, the above reference does not disclose modulation of the activity of JNK3. Chauhan et al. teach that interleukin-6

inhibits stress-activated protein kinase (SAPK) or c-Jun amino-terminal kinase (JNK) in multiple myeloma cells (see Title, abstract, page 227, column 2, 2nd para, Materials and Methods section and page 231 Figure 4, column 1 second para) and teach JNK activity assays (Figures 3 and 4). The reference does not teach specifically a method for assaying for modulators of the activity of JNK3. However, it appears that all JNK isoforms were included in the experiment.

It would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of McKay et al. with that of Chauhan et al. to develop a method of identifying modulators of the activity of JNK3. McKay et al. teach that one would be motivated to do this as inhibition of JNK activity results in decreased AP-1 activity leading to inhibition of abnormal cell proliferation and tumor proliferation, development and maintenance (see column 1, lines 25-30). One would have a reasonable expectation of success since McKay et al. teach assays for modulators of expression of all the three isoforms of JNK and Chauhan et al. teach the methods of assaying JNK by JNK activity.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art to have performed the claimed invention.

6. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al., and McKay et al. (US 5,877,309 dated 3-2-1999, filed on 8-13-1997). Claims 5-6 are drawn to a method of identifying a compound that modulates JNK3 binding to its substrate. Gupta et al. teach a method for determination of binding of JNK3 to its substrate and conclude c-Jun being

an excellent substrate for JNK3 among two other substrates tested (see figure 5). The reference also teaches methods to determine the binding of JNK1 and JNK2 to their substrates. However, Gupta et al. does not teach identification of compounds that modulate the binding of JNK3 to its substrate.

With the high level of knowledge existing in the art, it would have been obvious to one skilled in the art at the time the invention was made to take the teachings of Gupta et al. and develop a method for identifying a compound that can inhibit the binding reaction of Gupta et al. comprising a simple incubation of the above binding reaction of Gupta et al. with and without the compound of interest and determine whether binding occurred or not. McKay et al. teach that one would be motivated to do this as inhibition of JNK activity (which can be brought about by preventing it from binding to its substrate) results in decreased AP-1 activity leading to inhibition of abnormal cell proliferation and tumor proliferation, development and maintenance (see column 1, lines 25-30). One would have a reasonable expectation of success since Gupta et al. teach methods to perform binding reaction with all the three isoforms of JNK.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art to have performed the claimed invention.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

REBECCA E. PRUITY
PRIMARY EXAMINER
GROUP ~~1600~~ 1605

Manjunath N. Rao

September 1, 2000